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DATE: March 24, 2017

TO: Interested Parties

FROM: Stefanie Nadeau, Director, MaineCare Services

SUBJECT: MAJOR SUBSTANTIVE RULE
ROUTINE TECHNICAL RULE
14-118 C.M.R. Chapter 11, Rules Governing the Controlled Substances Prescription Monitoring Program and Prescription of Opioid Medications

Although the Maine Legislature in P.L. 2011, ch. 657, Part AA, § 71, as codified in 22 M.R.S. § 7252, designated Prescription Monitoring Program (PMP) rulemaking as major substantive rules, P.L. 2015, ch. 488 designated some of its PMP rule changes as routine technical.

This letter gives notice of a rulemaking for Chapter 11, Rules Governing the Controlled Substances Prescription Monitoring Program and Prescription of Opioid Medications. This rulemaking finally adopts the routine technical changes, and provisionally adopts the major substantive changes.

In an effort to combat the Maine opioid epidemic, the Maine Legislature enacted P.L. 2015, ch. 488 (An Act to Prevent Opiate Abuse by Strengthening the Controlled Substances Prescription Monitoring Program). P.L. 2015, ch. 488 to amend the Prescription Monitoring Program (PMP)(Title 22, Chapter 1603) to include prescriber limits on opioid medication prescribing, effective January 1, 2017; included veterinarians in the definition of prescribers; required electronic prescribing and required prescribers and dispensers to check the Prescription Monitoring Program (PMP) database. Ch. 488 required the Department to establish reasonable exceptions to prescriber limits, and ordered the Department to include prescribers in the process of drafting appropriate exceptions and in the drafting of draft rules. With the guidance of the Maine State Health Officer Dr. Christopher Pezzullo, the Department convened a PMP Stakeholder Group that included the Maine Medical Association, the Maine Hospital Association, the Maine Physician Assistant Association, the Maine Nurse Practitioners Association, the Maine Veterinary Medical Association, the Maine Pharmacy Association, and the Maine Osteopathic Association. This Group met at least once monthly, starting in June, 2016. The Maine Legislature mandated a January 1, 2017, effective date for the limits on opiate prescribing, but also mandated that the Department confer with the PMP Stakeholder Group, which continued to meet and confer until early December.

In order to comply with the Legislature's mandates, including the January 1, 2017 effective date deadline, the Department adopted an Emergency Major Substantive/Routine Technical rule, with an effective date of January 1, 2017.

Pursuant to 5 M.R.S. Sec. 8073, emergency major substantive rule provisions may be effective for up to twelve months or until the Legislature has completed review of the rules. Pursuant to 5 M.R.S. Sec. 8054, the emergency routine technical rule provisions are effective for up to 90 days.

This rulemaking makes permanent the emergency routine technical rule provisions of the January 1, 2017 emergency rule.

This rulemaking also provisionally adopts the emergency major substantive rule provisions of the January 1, 2017 emergency rule. This rulemaking will be submitted to the Maine Legislature for its review. Until the Maine Legislature completes its review of this rule, the January 1, 2017 Emergency rule will remain in effect with regard to its major substantive provisions.

The routine technical provisions of this rule, which are made finally effective by this rulemaking adoption, are **bolded** in the rule, and also marked “routine technical” in the left hand margin.

A public hearing was held by the Department on February 16, 2017. Additionally, 89 written comments were submitted during the comment period.

This adopted rulemaking makes the following changes:

- (1) Adds definitions (including definitions for “administer”, “acute pain”, “Benzodiazepine”, “chronic pain”, “hospital”, “opioid medication”, “serious illness” and also includes veterinarians in the definition of “prescribers”;
- (2) Adds general requirements for prescribing and dispensing, including the requirement that all prescribers must acquire DEA numbers and include the DEA number on each prescription, and includes exemption codes to match the exemptions from the opioid limitations set forth in the rule;
- (3) Requires prescribers, dispensers and veterinarians to register as PMP data requesters;
- (4) Requires prescribers include a designation on the prescription as to whether the prescription is for the treatment of acute or chronic pain.
- (5) Indicates the statutory requirement regarding electronic prescriptions and waivers of such;
- (6) Requires that dispensers report information to the PMP by electronic means and indicates the statutory waivers of such;
- (7) Requires prescribers, dispensers and veterinarians to check the PMP system;
- (8) Indicates the statutory limits on opioid medication prescribing;
- (9) Defines exemptions to limits on opioid medication prescribing;
- (10) Authorizes the Department to provide and receive PMP data from another state or Canadian province that has entered into an agreement with the Department for such sharing;
- (11) Establishes civil violations for prescribers and dispensers;
- (12) Establishes administrative sanctions for prescribers and dispensers;
- (13) Establishes standards for immunity from liability for disclosure of information;
- (14) Establishes standards for immunity from liability for a pharmacist which might result from dispensing medication in excess of the limit, if such dispensing was done in accordance with a prescription issued by a practitioner;
- (15) Authorizes the Department to verify and audit prescriber and dispenser compliance with the rules; and

Finally, as a result of public comments and further review by the Department and the Office of the Attorney General, there were additional technical changes, formatting updates, and changes to language for clarity. The Summary of Public Comments and Department Responses document identifies any changes that were made to the final rule.

Rules and related rulemaking documents may be reviewed at, or printed from, the Office of MaineCare Services website at <http://www.maine.gov/dhhs/oms/rules/index.shtml> or for a fee, interested parties may request a paper copy of rules by calling (207) 624-4050 or call Maine Relay at 711.

A concise summary of the adopted rule is provided in the Notice of Agency Rulemaking Proposal, which can be found at <http://www.maine.gov/sos/cec/rules/notices.html>. This notice also provides information regarding the rulemaking process.

Notice of Agency Rule-making Adoption

AGENCY: Department of Health and Human Services, Maine Office of Substance Abuse & Mental Health Services

CHAPTER NUMBER AND TITLE: 14-118 C.M.R. Chapter 11, Rules Governing the Controlled Substances Prescription Monitoring Program and Prescription of Opioid Medications

ADOPTED RULE NUMBER:

CONCISE SUMMARY:

In an effort to combat the Maine opioid epidemic, the Maine Legislature enacted P.L. 2015, ch. 488 (An Act to Prevent Opiate Abuse by Strengthening the Controlled Substances Prescription Monitoring Program). P.L. 2015, ch. 488 to amend the Prescription Monitoring Program (PMP)(Title 22, Chapter 1603) to include prescriber limits on opioid medication prescribing, effective January 1, 2017; included veterinarians in the definition of prescribers; required electronic prescribing and required prescribers and dispensers to check the Prescription Monitoring Program (PMP) database. Ch. 488 required the Department to establish reasonable exceptions to prescriber limits, and ordered the Department to include prescribers in the process of drafting appropriate exceptions and in the drafting of draft rules. With the guidance of the Maine State Health Officer Dr. Christopher Pezzullo, the Department convened a PMP Stakeholder Group that included the Maine Medical Association, the Maine Hospital Association, the Maine Physician Assistant Association, the Maine Nurse Practitioners Association, the Maine Veterinary Medical Association, the Maine Pharmacy Association, and the Maine Osteopathic Association. This Group met at least once monthly, starting in June, 2016. The Maine Legislature mandated a January 1, 2017, effective date for the limits on opiate prescribing, but also mandated that the Department confer with the PMP Stakeholder Group, which continued to meet and confer until early December.

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- (7) Requires prescribers, dispensers and veterinarians to check the PMP system;
- (8) Indicates the statutory limits on opioid medication prescribing;
- (9) Defines exemptions to limits on opioid medication prescribing;
- (10) Authorizes the Department to provide and receive PMP data from another state or Canadian province that has entered into an agreement with the Department for such sharing;
- (11) Establishes civil violations for prescribers and dispensers;
- (12) Establishes administrative sanctions for prescribers and dispensers;
- (13) Establishes standards for immunity from liability for disclosure of information;
- (14) Establishes standards for immunity from liability for a pharmacist which might result from dispensing medication in excess of the limit, if such dispensing was done in accordance with a prescription issued by a practitioner;
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[HTTP://WWW.MAINE.GOV/DHHS/OMS/RULES/INDEX.SHTML](http://www.maine.gov/dhhs/oms/rules/index.shtml) for rules and related rulemaking documents.

EFFECTIVE DATE:	March 31, 2017
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14	DEPARTMENT OF HEALTH AND HUMAN SERVICES
118	OFFICE OF SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES
Chapter 11:	RULES GOVERNING THE CONTROLLED SUBSTANCES PRESCRIPTION MONITORING PROGRAM AND PRESCRIPTION OF OPIOID MEDICATIONS

**RULES GOVERNING THE CONTROLLED SUBSTANCES PRESCRIPTION MONITORING
PROGRAM AND PRESCRIPTION OF OPIOID MEDICATIONS**

STATE OF MAINE



**DEPARTMENT OF HEALTH AND
HUMAN SERVICES
OFFICE OF SUBSTANCE ABUSE
AND MENTAL HEALTH SERVICES**

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NOTICE: Although the Maine Legislature designated the PMP rule as a major substantive rule, 22 M.R.S. Sec. 7252, the Maine Legislature in P.L. 2015, ch. 488 directed that some PMP rule provisions are routine technical rules. Accordingly, this rule contains both major substantive and routine technical provisions. The Routine Technical rule provisions are labeled accordingly in the left hand column, and also bolded, in order to differentiate them from the major substantive provisions.

Table of Contents

SECTION 1.	Introduction	2
SECTION 2.	Purpose	2
SECTION 3.	Definitions	2
SECTION 4.	General Requirements for Prescribing and Dispensing	6
SECTION 5.	Prescription Monitoring Program Requirements	8
SECTION 6.	Limits on Opioid Medication Prescribing and Exemptions to Limits	12
SECTION 7.	Access to Prescription Monitoring Information	13
SECTION 8.	Confidentiality	17
SECTION 9.	Review of Information	17
SECTION 10.	Penalties and Sanctions	18
SECTION 11.	Immunity from Liability	19
SECTION 12.	Audit	19

SECTION 1. Introduction

Legal basis: These rules are promulgated under the authority of 22 MRSA §7252, § 7523, §7254 and P.L. 2015, ch. 488.

Severance clause: The provisions of these rules are severable. If any provision of the rules is invalid, or if the application of the rules to any person or circumstances is invalid, such invalidity shall not affect other provisions or applications which can be given effect without the invalid provision or application.

SECTION 2. Purpose

These rules implement the controlled substances prescription monitoring program, established by the Legislature as a means to promote the public health and welfare and to detect and prevent substance abuse. These rules also implement requirements for the prescription of opioid medications.

SECTION 3. Definitions

1. Acute pain. Pain as defined by 22 MRSA §7246 1-A. Pain that is the normal, predicted physiological response to a noxious chemical or thermal or mechanical stimulus. Acute pain typically is associated with invasive procedures, trauma and disease and is usually time-limited.
2. Administer. An action to apply a prescription drug directly to a person by any means by a licensed or certified health care professional acting within that professional's scope of practice. "Administer" does not include the delivery, dispensing or distribution of a prescription drug for later use.
3. Authorized representative. A parent or guardian of a minor child, or a person who has been authorized pursuant to Article V of the *Maine Probate Code* to make health care decisions, or gain access to health care records, on behalf of another.
4. Benzodiazepine. Any of a specific group of drugs with a common chemical structure and pharmacological use, including certain antianxiety drugs, muscle relaxants, and sedatives. Common benzodiazepines include clonazepam (Klonopin), lorazepam (Ativan), and diazepam (Valium).
5. CFR. *The Code of Federal Regulations*. The *Code of Federal Regulations* is available at the State of Maine Law and Legislative Library, Maine State House, State Street, Augusta, Maine.
6. Chronic pain. Pain as defined by 22 MRSA §7246 1-C. Pain that persists beyond the usual course of an acute disease or healing of an injury and may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

7. Controlled substance. A drug or other substance included in schedules II, III or IV of 21 USC §812 (2004), or 21 CFR §1308 (2004).
8. Credentials. Information or a device provided by the office or their designee to a dispenser or prescriber that allows the dispenser or prescriber to electronically access prescription monitoring information. Credentials may include, but are not limited to, a username, password, or an identification device that generates a username or password.
9. Customer of the dispenser. A person seeking to have a prescription filled from a dispenser, has had a prescription partially filled by a dispenser, or has a prescription on file with the dispenser that has refills remaining.
10. Data requester. A prescriber, dispenser, or an individual duly authorized by a prescriber or dispenser, who registers with the Office or the Monitor, intending to search the prescription monitoring database for information regarding his or her own patients and customers.
11. Days' supply. The drug's intended duration, as defined by the prescriber, or the estimated number of days a prescription will last, based on the number of days a given prescription should last if taken according to the instructions.
12. Dispenser. A pharmacist who is licensed or registered under Title 32, Chapter 117 of *Maine Revised Statutes Annotated* or a licensed health care professional with authority to dispense or administer prescription drugs.
13. Dispenser identification number. The provider identification number issued to dispensing pharmacies by the National Council for Prescription Drug Programs or an equivalent, unique identification number assigned to a dispenser by the Office or the Monitor.
14. Emergency Department. The department of a hospital that provides medical services to patients requiring immediate care.
15. Generational suffix. An element of a patient name used to identify the patient by generation, such as but not limited to "junior," "senior," or "III."
16. Hospital. A facility licensed by the Department of Health and Human Services in Maine and defined under 22 MRSA §7932. 2-A, or licensed under the appropriate licensing agencies in the state where the hospital is located.
17. Inpatient Status. The specific admission status of a patient who has been admitted to the hospital and is receiving room, board and professional services in the hospital on a continuous twenty-four (24) hour-a-day basis.
18. Long Term Care Facility. An assisted living facility or nursing home.
19. Monitor. The entity designated by the Office to implement and manage the prescription monitoring program under the direction and oversight of the Office.
20. MRSA. The *Maine Revised Statutes Annotated*.

21. Office. The Maine Department of Health and Human Services, Office of Substance Abuse and Mental Health Services, as defined by 22 MRSA §7246, as amended.
22. Opioid Medication. A controlled substance containing an opioid and included in 21 United States Code, Section 812 or 21 Code of Federal Regulations, Part 1308.
23. Palliative Care. Palliative care is defined by 22 MRSA §1726(1)(A).
24. Patient. Either the person, or the owner or keeper of an animal, who is the ultimate user of a drug for whom a prescription is issued and/or for whom a drug is dispensed.
25. Patient address. The current geographic location of the patient's residence. If the patient's address is in care of another person or entity, the address of that person or entity must be provided in its entirety. When alternate addresses are possible, they must be recorded in the following order of preference:
 - A. The geographical location of the residence, as would be identified when a telephone is used to place a 9-1-1 call as described by Title 25, Chapter 352 of the *Maine Revised Statutes Annotated*, as amended;
 - B. A post office address issued by the United States Post Office;
 - C. The common name of the residence and town; or
 - D. The mailing address of the patient.
 - E. The address as listed on a valid state or federal ID.
 - F. If none of the above area available and the patient has no current residence, a notation that the patient is homeless is available.
26. Patient date of birth. The date of birth of the ultimate user of the drug or the date of birth of the owner or keeper of an animal for whom a drug is issued or dispensed, as recorded by the Department's Office of Vital Statistics.
27. Patient identification number. The unique number used to identify a particular person by the dispenser.
28. Patient name. The name of the patient for whom a prescription is ordered and must be recorded in the following format: Surname, first or given name, middle initial, generational suffixes if any.
29. Prescriber. As defined by 22 MRSA §7246, a licensed health care professional with authority to prescribe controlled substances or a veterinarian licensed under Title 31, Chapter 71-A with authority to prescribe controlled substances.
30. Prescriber identification number. The unique number issued to authorized prescribers of controlled substances by the Drug Enforcement Administration, United States Department of Justice, to authorized prescribers of controlled substances.

31. Prescriber's care. A patient is considered under a prescriber's care for the purpose of accessing data within the Prescription Monitoring Program when that patient has been referred to the prescriber, has had an in-person professional medical consultation with that prescriber within the past three years, or has an appointment for such a consultation.
32. Prescription monitoring information. As defined by 22 MRSA §7246, information submitted to and maintained by the program.
33. Program. The Controlled Substances Prescription Monitoring Program established under 22 MRSA §7248.
34. Public health district. One of the nine public health districts defined and established by 22 M.R.S.A. §§ 411(5) & 412(3).
35. Residential care facility. A private non-medical institution (PNMI), that provides shelter and personal care services to individuals.
36. Serious illness. Serious illness is defined by 22 MRSA §1726(1)(B).
37. Surname. The family name of a patient, including hyphenated family names.
38. USC. *The United States Code*. The *United States Code* is available at the Law and Legislative Library, Maine State House, State Street, Augusta, Maine.
39. Valid photographic identification
 - A. A valid Maine motor vehicle operator license;
 - B. A valid Maine identification card issued pursuant to Title 29-A M.R.S.A. §1410;
 - C. A valid United States passport; or
 - D. A valid passport or motor vehicle operator's license issued by another state, U.S. territory, U.S. possession or a foreign country, provided the passport or license:
 1. Contains a photograph of the traveler or licensee;
 2. Is encased in tamper-resistant plastic, or otherwise possesses indicia of tamper-resistance; and
 3. Identifies the date of birth of the traveler or licensee
 - E. Another currently valid state or federal ID that:
 1. Contains a photograph of the traveler or licensee;
 2. Is encased in tamper-resistant plastic, or otherwise possesses indicia of tamper-resistance; and
 3. Identifies the date of birth of the traveler or licensee

SECTION 4. General Requirements for Prescribing and Dispensing

A. Prescriber Requirements

1. This subsection applies to all prescribers as defined in the Definition section of this policy.
2. Prescriber Numbers
 - a. Each prescriber must acquire a DEA number. This number may be obtained from the U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control.
 - b. Prescribers must clearly indicate their DEA number on every prescription for a controlled substance written by the prescriber.
 - c. If U.S. Military affiliated prescribers with a service identification number do not have a valid DEA number, the prescriber's service identification number may be used. These providers must clearly indicate their service identification number on every prescription for a controlled substance written by the prescriber.
3. Prescription Code Requirement when the Prescription is Written for a Patient Under Treatment for Either Chronic or Acute Pain

The prescriber must designate whether a prescription is for the treatment of acute pain or chronic pain. The following designations should be used.

- i. For Acute pain, the word "Acute" should be written on the prescription
 - ii. For Chronic pain, the word "Chronic" should be written on the prescription
 - iii. For prescriptions using exemption code F (Acute pain for an individual with an existing opioid prescription for chronic pain), the word Acute should be used, as the seven (7) day limit applies.
4. Requirement to Include Diagnosis Code and Exemption Code
 - a. Diagnosis Code
 - i. All prescribers must include the diagnosis (ICD-10) code on the prescription for any opioid involving the Palliative Care Exemption.
 - ii. Diagnosis codes are not required on veterinary prescriptions

b. Exemption Code

- i. All prescribers must include the exemption code, if the member is claiming an exemption from the 100 Morphine Milligram Equivalent aggregate daily limit. The codes are as follows:**

Exemption Code A: Pain associated with active and aftercare cancer treatment. Providers must document in the medical record that the pain experienced by the individual is directly related to the individual's cancer or cancer treatment. An exemption for aftercare cancer treatment may be claimed up to six months post remission;

Exemption Code B: Palliative care in conjunction with a serious illness;

Exemption Code C: End-of-life and hospice care;

Exemption Code D: Medication-Assisted Treatment for substance use disorder;

Exemption Code E: A pregnant individual with a pre-existing prescription for opioids in excess of the 100 Morphine Milligram Equivalent aggregate daily limit. This exemption applies only during the duration of the pregnancy;

Exemption Code F: Acute pain for an individual with an existing opioid prescription for chronic pain. The seven day prescription limit applies; or

Exemption Code G: Individuals pursuing an active taper of opioid medications, with a maximum taper period of six months, after which time the opioid limitations will apply, unless one of the additional exceptions in this subsection apply.

Exemption Code H: Individuals who are prescribed a second opioid after proving unable to tolerate a first opioid, thereby causing the individual to exceed the 100MME limit for active prescriptions. For this exemption to apply, each individual prescription must not exceed 100 MME. In addition, the patient must bring the full remainder of the initial prescription to the pharmacy for collection prior to dispensation of the second prescription.

- ii. Exemption codes are not required on veterinary prescriptions.**

5. Requirement to Include Notation of Veterinary Prescription

All prescriptions intended for use by an animal must indicate such use on the prescription.

B. Dispenser Requirements

1. Dispenser Numbers

Dispensers must acquire and maintain an identification number issued to dispensing pharmacies by the National Council for Prescription Drug Programs (“NCPDP”), or request that an alternative number be assigned to them by the Monitor or the Office.

2. Partial Dispensing Authorized

Partial dispensing is authorized to the extent allowed by 32 MRSA §13786-B.

SECTION 5. Prescription Monitoring Program Requirements

A. Requirement to Register as PMP Data Requesters

1. Prescribers

All prescribers are required to register as data requesters with the Maine Prescription Monitoring Program.

2. Dispensers

All dispensers are required to register as data requesters with the Maine Prescription Monitoring Program.

3. Veterinarians

All veterinarians are required to register as data requesters with the Maine Prescription Monitoring Program.

B. Electronic Prescribing and Processing Requirements

1. Requirements for Prescribers

Prescribers must comply with the requirements regarding electronic prescription of opioids and waivers as set forth in:

32 MRSA §2210(3)
32 MRSA §2600-C(3)
32 MRSA §3300-F(3)
32 MRSA §4878(2)
32 MRSA §18308(3).

2. Requirements for Dispensers

Dispensers must follow the requirements regarding processing of electronic prescriptions for opioids as described in 32 MRSA §13756.

C. Requirement that Dispensers Report Information to the PMP by Electronic Means and Waiver of Requirement

1. No later than the close of business on the next business day after dispensing a controlled substance, dispensers must, via approved electronic submission, provide the following information to the Prescription Monitoring Program:
 - a. The dispenser identification number;
 - b. The dates the prescription was filled and delivered (issued);
 - c. The prescription number;
 - d. Whether the prescription is new or is a refill;
 - e. The National Drug Code (NDC) for the drug dispensed;
 - f. The quantity dispensed;
 - g. The dosage;
 - h. The patient identification number;
 - i. The patient name;
 - j. The patient address;
 - k. The patient date of birth;
 - l. The prescriber identification number; and
 - m. The date the prescription was issued by the prescriber.
 - n. The exemption code and ICD-10 code (for Palliative Care exemptions) if the aggregate daily limit exceeds 100 MME.
 - o. If the prescription is for an animal, a notation indicating such.
2. Dispensers must correct their own records and submit corrected copies of these records to the Program whenever they become aware of errors or omissions.
3. The Office may grant a waiver of the electronic submission requirement to a dispenser for good cause and according to the terms described in:

32 MRSA §2210(3)
 32 MRSA §2600-C(3)
 32 MRSA §3300-F(3)
 32 MRSA §4878(2)
 32 MRSA §18308(3).

D. Requirement to Check the Prescription Monitoring Program system.

1. **Prescriber Requirements**
 - a. **Prescribers must check the Prescription Monitoring Program system for records related to the person for whom the medication is being prescribed in accordance with the terms described in 22 MRSA §7253(1).**
 - b. In order to fulfill the requirement to check the Prescription Monitoring Program system, the prescriber must review the following information:

- i. Aggregate Morphine Milligram Equivalent for the person or whom the medication is being prescribed. The aggregate Morphine Milligram Equivalent is the total daily Morphine Milligram Equivalent for the individual, to include the anticipated new prescription.
- ii. The number of prescribers currently prescribing controlled substances to the individual; and
- iii. The number of pharmacies currently filling prescriptions for controlled substances for the individual.

2. **Exceptions.**

Prescribers are not required to check the Prescription Monitoring Program system when the conditions described in 22 MRSA §7253(3) have been met.

3. **Dispenser Requirements**

- a. **Dispensers must check the Prescription Monitoring Program system for records related to the person for whom the medication is being prescribed in accordance with the terms described in 22 MRSA §7253(2).** In order to fulfill the requirement to check the Prescription Monitoring Program system, the dispenser must review the following information:
 - 1. Aggregate MME for the person for whom the medication is being prescribed. The aggregate MME is the total MME for the individual, to include the anticipated new prescription.
 - 2. The number of prescribers currently prescribing controlled substances to the individual; and
 - 3. The number of pharmacies currently filling prescriptions for controlled substances for the individual.
 - 4. A dispenser shall notify the Office PMP coordinator and decline to fill a prescription until the dispenser is able to contact the prescriber of that prescription if the dispenser has reason to believe that the prescription is fraudulent or duplicative. Reasons to believe that the prescription is fraudulent or duplicative include, but are not limited to, lack of prior approval from the prescriber regarding any of the following:
 - i. Filling the new prescription would result in exceeding the limitations set forth in 32 MRSA §2210(1), 32 MRSA §2600-C(1), 32 MRSA §3300-F(1), 32 MRSA §4878(1), or 32 MRSA §18308(1).
 - ii. Another prescriber is contemporaneously prescribing the same controlled substance to the individual.

- iii. Another pharmacy/dispenser is contemporaneously filling a prescription for the same controlled substance for the individual.

b. Exceptions

Dispensers are not required to check the Prescription Monitoring Program system when the conditions described in 22 MRSA §7253(3) have been met.

4. Veterinarian Requirements

- a. **Veterinarians must check the Prescription Monitoring Program system in accordance with the terms described in 22 MRSA §7253(1).** The following records must be checked:
 - i. Records related to the individual seeking care for the animal;
 - ii. If deemed appropriate by the prescriber, the records related to the owner of the animal, in the event the owner is not the individual seeking care for the animal.
- b. In order to fulfill the requirement to check the Prescription Monitoring Program system, the veterinarian must review the following information:
 - i. Aggregate Morphine Milligram Equivalent (MME) for the individual seeking care for the animal, or, if appropriate, the owner of the animal.
 - ii. The number of prescribers currently prescribing controlled substances to the individual; and
 - iii. The number of pharmacies currently filling prescriptions for controlled substances for the individual.
- c. In the event the prescribing veterinarian identifies concerns related to any of the following regarding the information found in the prescription monitoring program system, the veterinarian must contact the PMP coordinator.
 - i. Aggregate Morphine Milligram Equivalent for the individual seeking care for the animal, or, if appropriate, the owner of the animal.
 - ii. The number of prescribers currently prescribing controlled substances to the individual; and
 - iii. The number of pharmacies currently filling prescriptions for controlled substances for the individual.

5. Exceptions.

Veterinarians have twenty-four (24) hours after prescribing an opioid or benzodiazepine to check the Prescription Monitoring Program. When a veterinarian directly orders or administers a benzodiazepine or opioid medication to an animal in an emergency setting, the requirement to check the prescription monitoring information system does not apply. Veterinarians writing prescriptions to be filled upon discharge from an emergency setting must check the prescription monitoring information system.

SECTION 6. Limits on Opioid Medications Prescribing and Exemptions to Limits

A. LIMITS ON OPIOID MEDICATION PRESCRIBING

Prescribers are required to comply with limits on opioid medication prescribing as set forth in:

- 32 MRSA §2210(1) (Nurses and Nursing)
- 32 MRSA §2600-C(1) (Osteopathic Physicians)
- 32 MRSA §3300-F(1) (Board of Licensure in Medicine)
- 32 MRSA §18308(1) (Dental Professionals)
- 32 MRSA §4878(1) (Veterinarians)

B. EXEMPTIONS TO LIMITS ON OPIOID MEDICATION PRESCRIBING

Prescribers are exempt from the limits on opioid medication prescribing established in this rule if:

1. **Pain associated with active and aftercare cancer treatment. Providers must document in the medical record that the pain experienced by the individual is directly related to the individual's cancer or cancer treatment. An exemption for aftercare cancer treatment may be claimed up to six months post remission;**
2. **Palliative care in conjunction with a serious illness;**
3. **End-of-life and hospice care;**
4. **Medication-Assisted Treatment for substance use disorder;**
5. **A pregnant individual with an pre-existing prescription for opioids in excess of the 100 Morphine Milligram Equivalent aggregate daily limit. This exemption applies only during the duration of the pregnancy;**
6. **Acute pain for an individual with an existing opioid prescription for chronic pain. The seven day prescription limit applies;**

Routine
Technical

7. **Individuals pursuing an active taper of opioid medications, with a maximum taper period of six months, after which time the opioid limitations will apply, unless one of the additional exceptions in this subsection apply; or**
8. **Individuals who are prescribed a second opioid after proving unable to tolerate a first opioid, thereby causing the individual to exceed the 100MME limit for active prescriptions. For this exemption to apply, each individual prescription must not exceed 100 MME. In addition, the patient must bring the full remainder of the initial prescription to the pharmacy for collection prior to dispensation of the second prescription.**

SECTION 7. Access to Prescription Monitoring Information

1. By patients

- A. A patient, or a patients' authorized representative, may obtain a report listing all prescription monitoring information that pertains to the patient.
- B. A patient or a patient's authorized representative seeking access to prescription monitoring information described above must submit a written request for information in person at the office of the Monitor, or at any other place specified by the Monitor or the Office. The written request shall be in a format established by the Office or the Monitor and shall contain at least, but not limited to, the following elements:
 - 1) the patient's name and the full name of the patient's authorized representative, if applicable;
 - 2) the patient's date of birth;
 - 3) the patient's address, and the complete physical address of the patient's authorized representative, if applicable;
 - 4) the patient's telephone number, if any, and the telephone number of the authorized representative, if applicable; and
 - 5) the time period for which information is being requested.
- C. The patient or the patient's authorized representative must produce valid photographic identification prior to obtaining access to the information described above. The patient or the patient's authorized representative must allow photocopying of the identification.
- D. Prior to obtaining access to the information described above, authorized representatives must produce either an official attested copy of the judicial order granting them authority to gain access to the health care records of the patient; or in the case of parents of a minor child, a certified copy of the Birth Certificate of the

minor child or other official documents establishing legal guardianship; or in the case of persons holding power of attorney, the original document establishing the power of attorney. The patient's authorized representative must allow photocopying of the documents described above. The Office or the Monitor may verify the patient authorization by any reasonable means prior to providing the information to the authorized representative.

2. By dispensers

- A. A dispenser, a licensed pharmacy technician authorized by a supervising pharmacist, or a staff member of a dispenser who is authorized by the dispenser on duty may obtain any prescription monitoring information insofar as the information relates to a customer of the dispenser seeking to have a prescription filled. The information shall be provided in a format established by the Office, which may include, but is not limited to, delivery by electronic means, facsimile transmission, or telephonic communication.
- B. A dispenser who seeks access to the information described above must register as a data requester in a manner specified by the Monitor or the Office. The Office or Monitor shall issue credentials to authorized dispensers. Dispensers may use these credentials to access the online database and submit requests. If the credentials issued by the Office are lost, missing, or the security of the credentials is compromised, the dispenser shall cause the Office or Monitor to be notified by telephone and in writing as soon as reasonably possible. Information regarding more than one customer may be submitted in a single request. Requests shall be in a format established by the Office or the Monitor and shall contain at least, but not limited to, the following elements for each customer:
 - 1) The name and date of birth of the customer; and
 - 2) The time period for which information is being requested.
- C. The Office or the Monitor shall take reasonable steps to verify each registration, such as, but not limited to, making a telephone call to the dispenser or to an agent of the dispenser at a telephone number known to belong to the dispenser's place of business.

3. By prescribers

- A. A prescriber, or any staff member duly authorized by a prescriber and the Office, or any staff member of a licensed hospital who is authorized by the chief medical officer of the hospital, may obtain any prescription monitoring information insofar as the information relates to a patient under the prescriber's care, or patient receiving care in the hospital's emergency department or receiving inpatient services from the hospital. The information shall be provided in a format established by the Office, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.
- B. A prescriber, or any staff member duly authorized by a prescriber and the Office, who seeks access to the information described above must register as a data requester in a manner specified by the Monitor or the Office. The Office or

Monitor shall issue credentials to authorized prescribers or their designees. Data requesters may use these credentials to access the online database and submit requests. If the credentials issued by the Office are lost, missing, or the security of the credentials is compromised, the data requester shall cause the Office or Monitor to be notified by telephone and in writing as soon as reasonably possible. Requests shall be in a format established by the Office or the Monitor and shall contain at least, but not limited to, the following elements for each patient:

- 1) The name and date of birth of the patient; or the individual seeking care for and/or owner of an animal for whom a drug is issued or dispensed; and
 - 2) The time period for which information is being requested.
- C. The Office or the Monitor shall take reasonable steps to verify each registration, such as, but not limited to, making a telephone call to the prescriber and licensed health care practitioners duly authorized by prescribers, or to an agent of the prescriber at a telephone number known to belong to the prescriber's place of business.
4. By executive director, board investigator, or person authorized to discharge equivalent functions of a licensing board.
 - A. An executive director, board investigator, or person authorized to discharge equivalent functions of a licensing board with jurisdiction over a dispenser or prescriber may obtain any prescription monitoring information as required for an investigation, with reasonable cause. The information shall be provided in a format established by the Office, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.
 - B. An executive director, board investigator, or person authorized to discharge equivalent functions of a licensing board with jurisdiction over a dispenser or prescriber who seeks access to prescription monitoring information described above must submit a request via mail, facsimile, or secure electronic transmission, to a location specified by the Monitor or the Office. The request shall contain identifying information regarding the licensee or patient and the time period for which the information is being requested. The data requester shall certify that each request is related to an investigation involving misuse of a Schedule II, III, or IV drug and provide a case number or other assurance that the request is related to the board representative's official duties.
 5. By personnel of any vendor or contractor engaged by the Office
 - A. Personnel of any vendor or contractor engaged by the Office may obtain any prescription monitoring information insofar as the information is necessary for establishing and maintaining the program's electronic system.
 - B. The Office, the monitor, and program vendors or contractors engaged by the Office, shall purge all prescription monitoring information more than six years old.
 6. By the units within the Department of Health and Human Services that administer the MaineCare program

- A. Subject to the requirements of 22 M.R.S.A. §7250(4)(F), the authorized representative of those units of the Department of Health and Human Services which oversee, administer, or otherwise supervise MaineCare programs which determine eligibility for and use of prescription drugs, and the appropriate utilization of prescription drugs, may obtain any prescription monitoring information insofar as the information is necessary for the purposes of managing the care of MaineCare members, monitoring the purchase of controlled substances by MaineCare members, and avoiding duplicate dispensing of controlled substances to MaineCare members.
 - B. The person or persons authorized pursuant to Section 7(6)(A) must submit a request via mail, facsimile, or secure electronic transmission, to a location specified by the Monitor or the Office. The request shall contain surname, first name, and date of birth of the member and the time period for which the information is being requested. An intervention approach shall be undertaken with MaineCare members who are determined to be accessing controlled substances in a quantity or with a frequency beyond the norm for persons with similar medical conditions or diagnoses and the intervention approach shall not include terminating the member from MaineCare services.
7. By the Office of the Chief Medical Examiner
- A. The Chief Medical Examiner or a designee may obtain any prescription monitoring information as required for an investigation or inquiry into the cause, manner and circumstances of death in a medical examiner case. The information shall be provided in a format established by the Office of Substance Abuse, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.
 - B. The Chief Medical Examiner or a designee must submit a request via mail, facsimile, or secure electronic transmission, to a location specified by the Monitor or the Office. The request shall contain the surname, first name, and date of birth of the decedent and the time period for which the information is being requested.
8. By Other States and Canadian Provinces

The Department may provide prescription monitoring information to and receive prescription monitoring information from another state or a Canadian province that has prescription monitoring information provisions consistent with this regulation and that has entered into a prescription monitoring information sharing agreement with the Department.

The Department may enter into a prescription monitoring information agreement with another state or a Canadian province to establish the terms and conditions of prescription monitoring information sharing and interoperability of information systems and to carry out the purposes of this rule.

For purposes of this rule, “another state” means any state other than Maine and any territory or possession of the United States, but does not include a foreign country.

SECTION 8. Confidentiality

1. Pursuant to 22 MRSA §7250(1), prescription monitoring information is confidential and not a public record as defined in Title 1, section 402, subsection 3. Breaches of the confidentiality may result in criminal prosecution and/or administrative sanctions.
2. Pursuant to 22 MRSA §7250(3), the Office may provide de-identified copies of prescription monitoring information to researchers who have signed written agreements restricting the use of the data for research, policy, or educational purposes. The Office may make aggregate information based on prescription monitoring information available to the public.
3. The Office shall periodically conduct an audit review of the Monitor for compliance with the terms of the contract regarding confidentiality of information concerning the prescription drug, prescriber, pharmacy, patient and dispenser.
4. The Monitor shall fully cooperate with the Office in any audit review conducted pursuant to Subsection 3.
5. The Office and the Monitor shall purge from the database all prescription monitoring information that is older than six (6) years old.

SECTION 9. Review of Information

1. Pursuant to 22 MRSA §7250, the Office and the Monitor shall review the information in the database on at least a quarterly basis to determine whether there are cases in which there has been questionable activity by patients or prescribers.
2. The Office shall review prescription monitoring information related to individual patients to determine which patients have surpassed threshold levels of controlled substances. These threshold levels may include any of the following but are not limited to—
 - high number of prescribers in a short time period, as determined by the Office;
 - high number of doses during a short time period, as determined by the Office;
 - Days Supply of prescriptions for the same drug overlapping by more than a few days;
 - inappropriate combinations of controlled substances, as determined by the Office;
 - more than one method of payment within a short time period;
 - more than one out of state prescriber for the same patient, during a short time period, as determined by the Office;
 - more than one pharmacy on the same day;

- more than one pharmacy in different public health districts within one month; AND/OR
- dangerous levels of specific drugs, as determined by the Office.

Notification – When a patient surpasses the threshold levels established by the Office, the office shall notify the prescriber(s) and the dispenser(s) of the controlled substance(s) and provide all relevant prescription monitoring information to those persons through an established letter of notification.

SECTION 10. Penalties and Sanctions

- A. Criminal penalties. A person who intentionally or knowingly uses or discloses prescription monitoring information in violation either of Title 22, M.R.S.A. Ch. 1603 or these rules, unless otherwise authorized by law, shall be subject to the criminal penalties established in 22 MRSA §7251(2).

B. Civil violations

1. Prescribers

A prescriber who fails to adhere to the opioid prescribing rules as described in this rule or who fails to check the prescription monitoring system as required by this rule and by statute commits a civil violation for which a fine of \$250 per violation, not to exceed \$5,000 per calendar year, may be adjudged.

2. Dispensers

A dispenser who knowingly fails to submit prescription monitoring information to the Office or who fails to check the prescription monitoring information system as required by this rule and by statute commits a civil violation for which a fine of \$250 per incident, not to exceed \$5,000 per calendar year, may be adjudged.

C. Administrative sanctions

1. State Reporting

The Department will notify the appropriate licensing entity in the event that any prescriber or dispenser violates the terms of this rule. Prescribers or dispensers will receive two (2) weeks advance notice and opportunity to comment in the event the Department intends to contact the appropriate licensing entity regarding a violation.

2. Prescribers

A prescriber who fails to adhere to the opioid prescribing rules as described in this rule or to check the prescription monitoring information system as required by this rule and by statute is subject to discipline by the state licensing entity responsible for oversight of the prescriber's license.

3. Dispensers

A dispenser who knowingly fails to submit prescription monitoring information to the Office as required by this rule or by statute is subject to discipline by the Maine Board of Pharmacy pursuant to Title 32, chapter 117, subchapter 4 or by the applicable professional licensing entity.

SECTION 11. Immunity from Liability

- A. A dispenser or prescriber, including a veterinarian, is immune from liability for disclosure of information if the disclosure was made pursuant to and in accordance with these rules.
- B. A pharmacist who dispenses opioid medication in good faith is immune from any civil liability that might otherwise result from dispensing medication in excess of the limit established in this rule, if the prescription was dispensed in accordance with a prescription issued by a practitioner.
- C. In a proceeding regarding immunity from liability, there is a rebuttable presumption of good faith.

SECTION 12. Audit

The Department has the authority to verify and/or audit prescriber and dispenser compliance with these rules.

STATUTORY AUTHORITY: 22 MRSA Ch. 1603, Resolve 2005 ch. 36

EFFECTIVE DATE:

June 22, 2004 – filing 2004-225, EMERGENCY, effective for 90 days

June 26, 2005 – filing 2005-192

AMENDED:

June 9, 2010 – filing 2010-186 (Final adoption, major substantive)

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July 11, 2015 – filing 2015-108 (Final adoption, major substantive)

NOTICE: Although the Maine Legislature designated the PMP rule as a major substantive rule, 22 M.R.S. Sec. 7252, the Maine Legislature in P.L. 2015, ch. 488 directed that some PMP rule provisions are routine technical rules. Accordingly, this rule contains both major substantive and routine technical provisions. The Routine Technical rule provisions are labeled accordingly in the left hand column, and also bolded, in order to differentiate them from the major substantive provisions.